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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICANT : Jackowski et al.

INVENTION : Biopolymer Marker Indicative Of
Disease State Having A Molecular
Weight Of 1350 Daltons

SERIAL NUMBER : 09/845,729

FILING DATE : April 30, 2001

EXAMINER : Cook, Lisa V.

GROUP ART UNIT : 1641

OUR FILE NO. : 2132.031

CERTIFICATE UNDER 37 CFR 1.8(a)

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DECLARATION UNDER 37 CFR § 1.132

I, Ferris H. Lander, do hereby declare as follows:

1. I am a registered Patent Agent and am authorized to represent the inventor's and assignee in the application entitled "Biopolymer Marker Indicative of Disease State Having A Molecular Weight of 1350 Daltons", having U.S. Application Serial No. 09/845,729, filed April 30, 2001.

2. In the Office Action mailed on March 11, 2003, claims 3-9, 18-28 and 33-35 (as originally presented) were rejected under 35 U.S.C. 112, first paragraph because the claimed invention allegedly

contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims as amended have been limited to a specific biopolymer marker peptide consisting of amino acid residues 2-14 of SEQ ID NO:1 (the 1350 dalton marker) useful in methods and kits for diagnosing myocardial infarction or renal failure. The method of the invention as recited in claim 36 involves a comparison of the mass spectrum profile of a peptide consisting of amino acid residues 2-14 of SEQ ID NO:1 to mass spectrum profiles of peptides elucidated from a patient sample, wherein recognition of a mass spectrum profile in the patient sample displaying the characteristic profile of the mass spectrum of the peptide consisting of amino acid residues 2-14 of SEQ ID NO:1 indicates that the patient from which the sample was obtained is suffering from myocardial infarction or renal failure .

3. In order to provide data which would further support the comparison step involved in the claimed method, I contacted Dr. George Jackowski, Chief Executive Officer and Chief Science Officer of Syn-x Pharma Inc., and asked to be provided with evidence of the absence of the 1350 dalton marker in normal human sera (obtained from healthy patients).

4. This declaration (including the attached figure) is provided in order to show a comparison of the serum profile of an individual having myocardial infarction to the serum profile of a non-diseased individual, so as to evidence that the marker (the

1350 dalton peptide) was not present in normal human sera.

The attached figure, obtained from Dr. Jackowski, provides side-by-side profiles (obtained using techniques of mass spectrometry) of normal human sera versus sera from patients having myocardial infarction. This profile comparison clearly evidences the absence of the 1350 dalton marker in normal human sera. This figure does not represent results obtained from additional experimentation. The profiles were reproduced from data obtained in the original experiments performed at the time of the invention.

The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application or any patent issuing thereon.

9/29/2003
Date

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